

**REMARKS**

Claims 1-17 are pending in this application. Claims 1, 8 and 14 have been amended. No new matter has been introduced.

Claims 1 and 7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Alten (U.S. Patent No. 4,852,554) ("Alten") in view of AORN Journal, *Association of Operating Room Nurses*, May 2000, Vol. 71, No. 5; Research Library ("AORN"). This rejection is respectfully traversed.

The claimed invention relates to a method of providing a customer-oriented integrated product and service package for a surgical procedure. As such, amended independent claim 1 recites a method of "providing a customer-oriented integrated product and service package for a surgical procedure" by *inter alia* "customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to predetermined specifications and conditions of a patient and of the predetermined surgical procedure undergone by the patient." Amended independent claim 1 also recites "loaning graft specific surgical instrumentation to match specifications of the allograft and the procedure."

Alten relates to "orthopedic prosthesis devices for cadavers comprised of plastic tubing, elbows and fasteners, for use by undertakers and morticians." (Abstract). Alten teaches that the devices "are used in cadavers whose bones have been harvested for bone banks, in order to give the cadaver a normal appearance." (Abstract).

AORN relates to "flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning." (p. 1061). Specifically, AORN addresses questions and answers from nurses in operating rooms

regarding sterilization of instruments or problems "the FDA has become aware . . . with cleaning, disinfecting, or sterilizing items leased by facilities." (p. 1062).

The subject matter of claims 1 and 7 would not have been obvious over Alten and AORN, whether considered alone or in combination. Neither Alten nor AORN discloses, teaches or suggests all limitations of amended independent claim 1. Alten does not disclose, teach or suggest "customizing an allograft to be used in a predetermined surgical procedure," much less "customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to predetermined specifications and conditions of a patient and of the predetermined surgical procedure undergone by the patient," as claim 1 recites. Alten teaches reconstructive orthopedic devices for cadavers and not customizing allografts to be used in predetermined surgical procedures. The crux of Alten is orthopedic devices for cadavers with no internal structure remaining within the cadaver to support the skin after the bones are removed (Col. 1, ll. 53-55), and not a method of providing a customer-oriented integrated product and service package for a surgical procedure, as in the claimed invention.

In the March 21 and August 9, 2006 Office Actions, the Examiner asserts that "Alten discloses . . . customizing an allograft to a predetermined surgical procedure (abstract and col. 1, lines 45-62 of Alten)." (March 21, 2006 Office Action at 3). Applicants submit that both the Abstract and Col. 1, ll. 45-62 of Alten are silent about "customizing an allograft," or about "customizing an allograft to be used in a predetermined surgical procedure," or about "customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to predetermined specifications and conditions of a patient and of the predetermined surgical procedure undergone by the patient," as in the claimed invention. As noted above, Alten relates to orthopedic devices for cadavers (that have no internal structure remaining within the

cadaver to support the skin after the bones are removed), and not to customized allografts or to methods of providing customer-oriented integrated product and service package for surgical procedures involving allografts.

Applicants further submit that Alten is silent about "loaning graft specific surgical instrumentation to match specifications of the allograft and the procedure," as amended independent claim 1 recites. Alten teaches reconstructive orthopedic devices for cadavers and not "customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to predetermined specifications and conditions of a patient and of the predetermined surgical procedure undergone by the patient" and "loaning graft specific surgical instrumentation to match specifications of the allograft and the procedure," as in the claimed invention.

AORN does not rectify the deficiencies of Alten. AORN fails to disclose any of the limitations of claims 1 and 7. AORN does not disclose, teach or suggest "customizing an allograft to be used in a predetermined surgical procedure," much less "customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to predetermined specifications and conditions of a patient and of the predetermined surgical procedure undergone by the patient" and "loaning graft specific surgical instrumentation to match specifications of the allograft and the procedure," as in the claimed invention. AORN relates to various issues raised by nurses in operating rooms regarding sterilization, cleaning, or disinfecting of instruments, and not to methods of providing a customer-oriented integrated product and service package for a surgical procedure, much less to a method of providing a customer-oriented integrated product and service package for a surgical procedure by the specific steps of claim 1. For at least these reasons, the Office Action fails to establish a *prima facie* case of obviousness, and withdrawal of the rejection of claims 1 and 7 is respectfully requested.

Claims 2 and 3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Alten in view of AORN and further in view of Tubo et al. (U.S. Patent No. 5,040,677) ("Tubo") and Hamada (U.S. Patent No. 6,425,920) ("Hamada"). This rejection is respectfully traversed.

Claims 2 and 3 depend on amended independent claim 1 and recite "coordinating delivery of the allograft to a medical facility at which the surgical procedure is to be performed with delivery of the surgical instrumentation" (claim 2) and that "the allograft is harvested at a tissue bank and delivered directly to the medical facility" (claim 3).

Tubo relates to a "container for the storage and distribution of a cultured epithelial, generally planar, living, skin wound dressing that allows the dressing to be gently removed by lifting perpendicular to a support surface in the container." (Abstract). The design of Tubo "minimizes handling of the graft dressing thereby promoting cell viability." (Abstract).

Hamada relates to a spinal fusion implant. Hamada teaches "surgical instrumentation, implants, bone graft material, and measurement equipment to enable a spine fusion procedure to proceed more accurately, efficiently and safely by allowing precision measurement of the characteristics of the intervertebral space, selection of and provision of new implants, placement of an intervertebral implant." (Abstract).

The subject matter of claims 2 and 3 would not have been obvious over Alten in view of AORN, Tubo and Hamada, whether considered alone or in combination. As noted above, Alten and AORN, alone or in combination, do not disclose, teach or suggest all limitations of amended independent claim 1.

Tubo and Hamada fail to rectify the deficiencies of Alten and AORN. Neither Tubo nor Hamada discloses, teaches or suggests "customizing an allograft to be used in a predetermined surgical procedure," much less "customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to predetermined specifications and conditions of a patient and of the predetermined surgical procedure undergone by the patient" and "loaning graft specific surgical instrumentation to match specifications of the allograft and the procedure," as amended independent claim 1 recites. Tubo teaches a container for storing and distributing a skin wound dressing, and not a method of providing a customer-oriented integrated product and service package for a surgical procedure. Hamada relates to systems and methods for spinal fusion surgery, and not to "customizing an allograft to be used in a predetermined surgical procedure," much less to "customizing an allograft to be used in a predetermined surgical procedure" and "loaning graft specific surgical instrumentation to match specifications of the allograft and the procedure," as amended independent claim 1 recites. For at least these reasons, the Office Action fails to establish a *prima facie* case of obviousness, and withdrawal of the rejection of claims 1 and 2 is respectfully requested.

Claims 4-6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Alten in view of AORN and further in view of Ramshaw et al. (U.S. Patent No. 5,791,907) ("Ramshaw"). This rejection is respectfully traversed.

Claims 4-6 depend on amended independent claim 1 and recite "training operating personnel in the use of the instruments and skills to perform the surgical procedure" (claim 4), "providing technical support during the procedure" (claim 5), and "providing for the presence of a trained representative knowledgeable in the use of the instruments and the performance of the surgical procedure at an operation location during the procedure" (claim 6).

Ramshaw relates to an "interactive medical training device" that includes "a computer system having a display, wherein the computer system is programmed to provide education and training in medical procedures, including laparoscopic surgical procedures." (Abstract). According to Ramshaw, "[T]his aspect is achieved by configuring the system to display, on a portion of the display, a video window" so that the video window "displays a prerecorded video segment illustrating a portion of a laparoscopic surgical procedure." (Abstract).

The subject matter of claims 4-6 would not have been obvious over Alten in view of AORN and Ramshaw, whether considered alone or in combination. As noted above, Alten and AORN, alone or in combination, do not disclose, teach or suggest all limitations of amended independent claim 1. Ramshaw fails to rectify the deficiencies of Alten and AORN. Ramshaw fails to disclose, teach or suggest "customizing an allograft to be used in a predetermined surgical procedure," much less "customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to predetermined specifications and conditions of a patient and of the predetermined surgical procedure undergone by the patient" and "loaning graft specific surgical instrumentation to match specifications of the allograft and the procedure," as amended independent claim 1 recites. Ramshaw teaches an interactive medical system for educating and training personnel in various medical procedures, and not customizing allografts, or loaning graft specific surgical instrumentation to match specifications of the allograft and the procedure, as in the claimed invention. For at least these reasons, the Office Action fails to establish a *prima facie* case of obviousness, and withdrawal of the rejection of claims 4-6 is respectfully requested.

Claims 8 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hamada in view of Tubo and further in view of AORN. This rejection is respectfully traversed.

Amended independent claim 8 recites a “method of providing a customer-oriented integrated product and service package for a surgical procedure” by *inter alia* “arranging for delivery of a customized allograft for a predetermined surgical procedure, the customized allograft being sized according to specifications and conditions of a patient and of the predetermined surgical procedure.” Amended independent claim 8 also recites “customizing a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure, wherein the customized surgical instrumentation kit is loaned to a customer for the performance of the surgical procedure.”

The subject matter of claims 8 and 13 would not have been obvious over Hamada in view of Tubo and AORN, whether considered alone or in combination. The Office Action fails to establish a *prima facie* case of obviousness. Hamada, Tubo and AORN, alone or in combination, do not disclose, teach or suggest all limitations of amended independent claim 8. Hamada does not disclose a “method of providing a customer-oriented integrated product and service package for a surgical procedure,” much less the steps of “arranging for delivery of a customized allograft for a predetermined surgical procedure, the customized allograft being sized according to specifications and conditions of a patient and of the predetermined surgical procedure” or “customizing a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure, wherein the customized surgical instrumentation kit is loaned to a customer for the performance of the surgical procedure.” Hamada teaches spinal fusion implants, and not the steps recited in claim 8. Tubo and AORN also fail to disclose, teach or suggest any of the limitations of claim 8. Withdrawal of the rejection of claims 8 and 13 is respectfully requested.

Claim 9 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hamada in view of Tubo and further in view of AORN and Alten. Claims 10-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hamada in view of Tubo and further in view of AORN and Ramshaw. These rejections are respectfully traversed.

Claims 9-12 depend on amended independent claim 8. None of the cited references discloses, teaches or suggests all limitations of amended independent claim 8. For at least these reasons, the Office Action fails to establish a *prima facie* case of obviousness, and withdrawal of the rejection of claims 9-12 is respectfully requested.

Claims 14-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Alten in view of Tubo and Ramshaw. This rejection is respectfully traversed.

Amended independent claim 14 recites a "method of providing a customer-oriented integrated product and service package for a surgical procedure" by *inter alia* "arranging for delivery of a customized allograft for a predetermined surgical procedure, the customized allograft being sized according to specifications and conditions of a patient and of the predetermined surgical procedure." Amended independent claim 14 also recites "providing technical support and/or customer support to operating personnel before and/or during performance of the predetermined surgical procedure."

Alten, Tubo and Ramshaw, alone or in combination, do not disclose, teach or suggest all limitations of amended independent claim 14. Alten teaches reconstructive orthopedic devices for cadavers and not the steps of "arranging for delivery of a customized allograft for a predetermined surgical procedure, the customized allograft being sized according to specifications and conditions of a patient and of the




predetermined surgical procedure” or “providing technical support and/or customer support to operating personnel before and/or during performance of the predetermined surgical procedure,” as in the claimed invention. Alten is silent about customized allografts to be used in a predetermined surgical procedure, as in the claimed invention. The crux of Alten is orthopedic devices for cadavers with no internal structure remaining within the cadaver to support the skin after the bones are removed (Col. 1, ll. 53-55), and not a method of providing a customer-oriented integrated product and service package for a surgical procedure.

Tubo and Ramshaw do not disclose any of the limitations of claim 14. Tubo teaches a container for storing and distributing a skin wound dressing, and not a method of providing a customer-oriented integrated product and service package for a surgical procedure. Ramshaw teaches an interactive medical system for educating and training personnel in various medical procedures, and not customizing allografts, or providing technical support and/or customer support to operating personnel before and/or during performance of the predetermined surgical procedure, as in the claimed invention. For at least these reason, the Office Action fails to establish a *prima facie* case of obviousness, and withdrawal of the rejection of claims 14-17 is also respectfully requested.

Allowance of the application is solicited.

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